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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Nobutaka Wakamiya

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Title: NOVEL COLLECTIN

Group Art Unit: 1632

Examiner: Peter Paras, Jr.

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date:

February 14, 2003

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RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This paper is filed in response to a second Office Action restricting the claims of the application. The Office Action (paper #13) was dated January 29, 2003, and set a shortened statutory period of one month for the response. In light of the remarks presented below, Applicants request withdrawal of the rejections and favorable reconsideration of the application.

I. Response to Restriction Requirement.

The Office Action dated January 29, 2003 vacated the previous restriction requirement dated October 2, 2002 because the Examiner inadvertently did not apply lack of unity practice. In the Office Action, the Examiner again set forth the same 10-way restriction requirement as follows:

Group I: Claims 38-52 and 71-80, drawn to an isolated polynucleotide as set forth in SEQ. ID. NO.:1, which encodes the polypeptide set forth in SEQ. ID. NO.: 2, a vector comprising the same polynucleotide, and a host cell comprising the same vector classified in classes 536, 536, 435, and 435 subclasses 23.1, 23.5, 320.1 and 325.

Group II: Claims 58-70, drawn to an isolated collectin polypeptide, classified in class 530, subclass 350.

Group III: Claim 81, drawn to a probe for screening for a collectin homolog, classified in class 536, subclass 24.31.

Group IV: Claims 85-86, drawn to a method for obtaining a collectin homolog comprising screening proteins that bind an antibody, classified in class 435, subclass 7.1.

Group V: Claims 87-88, drawn to a method of quantitative determination of a collectin comprising contacting a sample with an antibody, classified in class 435, subclass 4.

Group VI: Claim 89, drawn to an ELISA kit comprising an antibody against collectin, classified in class 530, subclass 387.1.

Group VII: Claims 90-92, drawn to a method for isolating a collectin from a sample with an antibody against collectin by affinity chromatography, classified in class 530, subclass 412.

Group VIII: Claim 93, drawn to a method for making a collectin polypeptide *in vitro*, classified in class 435, subclass 70.1.

Group IX: Claim 94, drawn to a transgenic non-human animal comprising a polynucleotide encoding a collectin peptide, classified in class 800, subclass 13.

Group X: Claims 95-96, drawn to a transgenic non-human animal comprising a disrupted collectin gene, classified in class 800, subclass 13.

Applicants again provisionally elect the invention of Group I, *i.*e., claims 38-52 and 71-80. As claims 53-57 were not restricted to any group, they are believed to belong with the elected Group I claims. This election is made with traverse.

II. Traversal of Restriction Requirement.

This application was filed in accordance with 35 U.S.C. §371, as a national phase application of PCT application No. PCT/JP99/04552. Accordingly, unity of invention (not restriction) practice is applicable.

As the Examiner noted,

> "the MPEP 37 C.F.R. 1.475 and 1.467 state that 'if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the

> other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a);' and 'if an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.'"

However, when making a lack of unity of invention requirement, the examiner must explain why each group lacks unity with each other group (i.e. why there is no single general inventive concept) specifically describing the unique special technical feature of each group. (M.P.E.P. §1893.03(d)). The Examiner still has not satisfied this burden.

Applicant respectfully requests that the restriction requirement be reconsidered in accordance with the Written Opinion and International Preliminary Examination Report received from the International Searching Authority for the counterpart PCT International Application of which this application is a national stage application (see Appendix A, previously submitted to the Office on February 26, 2001). In the aforementioned Opinion and Report, the application was found to have unity of invention for Claims 1-37 as originally filed. Claims 1-37 correspond to pending Claims 38-96 which were filed merely to improve grammar, place the claims in more conventional U.S. form, and minimize the filing fee by eliminating multiple dependencies in the original claims. Thus, for the foregoing reason, applicant requests that the restriction requirement be reconsidered and withdrawn.

Moreover, the claims of Groups I-X are linked and form a single general inventive concept under PCT Rule 13.1. The claims of provisionally elected Group I are directed to an isolated polynucleotide comprising nucleotide sequences of SEQ ID NO: 1, SEQ ID NO:4, and SEQ ID NO:5 and that encodes a polypeptide of SEQ ID NO:2. Groups II-X also contain this single general inventive concept of SEQ ID NOS: 1, 2, 4 and 5 of the Group I claims. Thus, the claims of Groups I-X are linked in that they all contain the single general inventive concept of SEQ ID NOS: 1, 2, 4 and 5. As the Examiner notes, Claims 82-84 are generic to groups IV-VII and therefore should be examined with any of Groups IV-VII. For the foregoing reason, reconsideration and withdrawal of the restriction requirement is requested.

Finally, even under restriction practice, applicant requests that the restriction requirement be reconsidered because the Examiner has not shown that a serious burden would be required to examine all of the claims. M.P.E.P. § 803 provides:

If the search and examination of an application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

Thus, for a restriction to be proper, the Examiner must satisfy the following two criteria: (1) that independent and distinct inventions are being claimed (35 U.S.C. § 121); and (2) that the search and examination of the entire application cannot be made without serious burden. See M.P.E.P. § 803.

Applicant respectfully submits that the Examiner has not shown that the criteria for a proper restriction requirement have been satisfied. Initially, the Examiner has not shown that it would be a serious burden to search and examine Groups I through X together. The mere fact that there are multiple claims in an application does not automatically merit a restriction requirement. The claims in Group II are all directed to a polypeptide which correspond to the collectin gene. A search relating to this polypeptide would significantly overlap with the search required for the methods of screening, assaying, isolating or making this polypeptide or antibodies to this polypeptide (*e.g.*, Groups IV, V and VII), the antibody kit (*e.g.*, Group VI), and a composition comprising a nucleotide sequence encoding the polypeptide (*i.e.*, the compositions of Groups I, III, IX, and X). The Examiner has not shown that an undue burden would be produced by the combined search.

Moreover, Applicant submits that such a restriction requirement would be inconsistent with current PTO practice based on the Commissioner's sua sponte decision to partially waive the requirements of 37 C.F.R. § 1.141 et seq. (see M.P.E.P. § 803.04). Those guidelines provide that up to 10 polynucleotides of unrelated sequence may be pursued in a single application. In the present application, the sequences at issue (SEQ ID NO:1, SEQ ID NO:4, and SEQ ID NO:5) are a collectin gene and its primers and not unrelated sequences. Moreover, this restriction requirement also is inconsistent with M.P.E.P. § 803.04, which addresses the propriety of restricting polynucleotides encoding different polypeptides. Again the polypeptide sequence at issue in the present case (SEQ ID NO:2) is encoded by the collectin gene. The Examiner has not provided any support for the assertion that primers of and a polynucleotide encoded from the same gene should be restricted as different inventions as that term is used in M.P.E.P. § 803.04. In fact, under unity of invention practice a claim to a protein and a claim to a DNA sequence encoding that protein exhibit corresponding technical features and unity between such claims is accepted. M.P.E.P. Administrative Instructions Under the PCT, Annex B, Part 2, Examples Concerning Unity of Invention,

Example 17. Accordingly, Applicant submits that restriction between claims in which the nucleotide sequences of SEQ ID NO:1, SEQ ID NO:4, and SEQ ID NO:5 and the polypeptide sequence of SEQ ID NO:2 are the single general inventive concept would be improper.

It is submitted that all claims are now in condition for allowance. Applicant respectfully requests an early and favorable notification thereof. Should the Examiner wish to discuss this response in further detail, Applicants invite the Examiner to telephone the undersigned representative.

Respectfully Submitted,

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February 14, 2003

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